K011129

JUL 11 2001

SIGN Surgical Implant Generation Network

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Lewis G. Zirkle, Jr., M.D. President

# Summary of Safety and Effectiveness
# SIGN IM Nail

## Substantial Equivalence Information

The SIGN IM Nail if similar to the following Devices:

1. Smith & Nephew "R-T Tibial Nail"
2. Smith & Nephew "R-T Delta Tibial Nail"
3. ACE Medical "AIM" Titanium Tibial Nail
4. Synthes "Universal Nail"

All of the devices listed above are similar in design to the SIGN IM Nail system. The safety and effectiveness of the SIGN IM Nail is based on a long history of use of these in the market place.

## Device Description

The SIGN IM Nail system includes Tibial nails, Screws and Instruments. All components are manufactured from stainless steel. This device is available with diameters of 8mm, 9mm, 10mm, 11mm, and 12mm in the following lengths: 270mm, 280mm, 300mm, 320mm, 340mm, 360mm, 380mm, 400. Each nail is made from a solid type 316, ASTM F138, stainless steel bar with distal and proximal bends. Each nail has two holes at both the distal and proximal ends to accept solid 4.5mm diameter cortical bone screws.

## Indications for use

The SIGN IM Nail is indicated for internal fixation of diaphyseal tibial fractures including Transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions.

The SIGN IM Nail may be removed upon fracture healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2001

Ms. Jeanne Dillner
Executive Director
SIGN, Inc.
2950 George Washington Way
Richland, Washington 99352

Re: K011129
Trade/Device Name: SIGN IM Nail
Regulation Number: 888.3020
Regulatory Class: II
Product Code: HSB
Dated: April 6, 2001
Received: April 13, 2001

Dear Ms. Dillner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011129

Device Name: SIGN IM Nail (Tibia Rod)

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurence of CDRH, Office of Device Evaulation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011129

(Optional Format 3-10-98)